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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,535	05/16/2005	Edouard Pelissier	BDL-68	4664

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EXAMINER	
HELM, CARALYNNE E	

ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,535	PELISSIER, EDOUARD	
	Examiner	Art Unit	
	CARALYNNE HELM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-36* is/are pending in the application.

4a) Of the above claim(s) *28-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/25/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Note to Applicant: References to paragraphs in non-patent literature refers to full paragraphs (e.g. 'page 1 column 1 paragraph 1' refers to the first full paragraph on page 1 in column 1 of the reference)

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on April 16, 2008 is acknowledged. The traversal is on the grounds that three limitations of the independent claim were not met: 1) the claimed composition of the PLGA polymer, 2) the glass transition temperature of the D-lactide and PLGA mixture, and 3) the intimate association of the active principle with the polymer. These arguments were not found to be persuasive.

The utility of PLGA at varying monomer ratios is well known in the biomedical and drug delivery art. As discussed by Jain et al. (Biomaterials 2000 21:2475-2490), these polymers have been synthesized and used since the 1960s. Further the characteristics of the polymers with varying monomer ratios have also complied and known for a number of years prior to the invention. Thus it would have been well within the technical grasp of one of ordinary skill to utilize obvious modifications of the Osaka et al. formulation, resulting in the use of PLGA that did exemplify the claimed monomer ratio.

Osaka et al. do not discuss the glass transition temperature of the mixture that results from the combination of D-lactide and PLGA. The specification gives no indication that the depression in glass transition achieved due to the presence of the lactic acid based plasticizer is caused by any special processing conditions. Both Osaka et al. and the instant disclosure provide a physical mixture of PLGA w a lactic acid oligomer. Polymers with the claimed monomer ratio would have been readily apparent to the ordinarily skilled artisan based on the

disclosure of Osaka et al. Absent evidence to the contrary, these compositions would be able to achieve a glass transition temperature within the claimed range.

Applicant is afforded the opportunity of being their own lexicographer. Instant claim 20 recites "...an active principle intimately associated with said support..." but the specification does not provide a particular definition for "intimately associated." Reliance on the ordinary and customary meaning of the terms used and the broadest reasonable interpretation of the language as a whole translates into this phrase meaning 'closely connected'. Such a connection would occur at an interface, as occurs in the applicant's interpretation of the Osaka et al. teaching. Thus the disclosure of Osaka et al. meets the limitation of an active principle "intimately associated" with a bioresorbable polymer support.

The requirement is still deemed proper and is therefore made FINAL.

Claims 28-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of Graham v. John Deere Co. have been fully considered and analyzed in the rejections that follow.

Claims 20-23 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berggren et al (U.S. Patent No. 5,620,700) in view of Webber et al. (Journal of Biomedical Materials Research 1998 41:18-29), Jain (Biomaterials 2000 21:2475-2490), Maspero et al. (European Cells and Materials 2001 1:28), Maspero (Biodegradable, open porous scaffolds for the prevention of alveolar bone loss after tooth extraction:CO_2-processing and in vitro behavior 2001), Boone et al. (U.S. PGPub No. 2004/0052992), and Sinclair et al. (U.S. Patent No. 5,252,642).

Berggren et al. teach a drug delivery device that includes a bioerodible polymer and exemplify copolymers of lactic acid with glycolic acid (PLGA) as one preferred polymer, where the ratio of monomers to one another ranges from 25/75 to 75/25 (see column 3 line 66-column 4 line 1, column 5 lines 59-66, column 6 lines 17-19, and 50-69; instant claim 20). These polymers are taught to be made using L-lactic acid as well as D,L-lactic acid which is known to yield an amorphous copolymer when coupled with glycolic acid (see column 6 lines 60-63 and Jain et al. page 2476 column 2 paragraph 1 lines 4-13; instant claim 20). Berggren et al. also exemplify a 50/50 PLGA where each monomer constitutes 50% of the polymer (see example 1; instant claims 20, 25 and 26). Local anesthetics are taught as particular drugs taught to be incorporated within the invention of Berggren et al. (see column 8 lines 51-54 and column 9 lines 3-4; instant claims 20-22). Berggren et al. go on to teach the need for the inclusion of a

plasticizer when PLGA is the polymer utilized in their invention (see column 9 lines 45-53; instant claim 20). The plasticizer is taught to be included at 5-30wt% (see column 9 lines 64-67; instant claims 21 and 27). Bergmann et al. also describe a particular embodiment where a plasticizer, 50/50 PLGA, and drug are intimately combined within the composition (see example 1; claim 20). Sodium chloride is also included in this formulation; however, Berggren et al. teach that the inclusion drug release regulating agents is optional. Since salts are known to modify the release kinetics of contained drugs from delivery devices, its exclusion from the formulation would have been an obvious modification to one of ordinary skill in the art at the time the invention was made as a means of optimizing the release kinetics of the device (see Webber et al. page 20 column 1 paragraph 4, figures 1 and 2; instant claim 20). Berggren et al. teach neither the use of lactic acid or a lactic acid oligomer as the particular plasticizer used nor the glass transition temperature of the plasticizer-polymer mixture.

Both Maspero and Maspero et al. discuss the reduction in glass transition temperature that occurs when a plasticizer is added to PLGA. Maspero et al. teach the combination of PLGA with a plasticizer such that the glass transition temperature of the combination is reduced below room temperature as well as the utility of such a combination in a drug release (delivery) system (see column 1 paragraph 1 and column 2 paragraphs 1 and 2; instant claim 20). Maspero teaches that the combination of the same plasticizer with 50/50 PLGA can result in a glass transition temperatures below 15°C (see figure 2.7). Although the Maspero references do not teach lactic acid or its oligomer as the particular the plasticizer used, they do teach that a plasticized 50/50 PLGA with the claimed glass transition temperature was known at the time of the invention for use in implantable biological applications.

Both Boone et al. and Sinclair et al. teach the utility of lactic acid and/or lactic acid oligomers as plasticizers for lactic acid based polymers. Sinclair et al. teach that lactide (a lactic

acid oligomer) was used as a placticizer for a PLGA film (see claims 19-24). Boone et al. teach that lactic acid, lactide, other lactic acid oligomers or mixtures thereof can be used as placticizers in poly(lactic acid) (see abstract and column 3 lines 57-65; instant claim 20). Thus it would have been obvious to one of ordinary skill in the art at the time the invention was made to use lactic acid, lactide, other lactic acid oligomers or mixtures thereof as the plasticizer in the invention of Berggren et al. Further, since it was known that achieving a glass transition temperature for plasticized PLGA below 15ºC was possible and, at times, desirable for implantable biological applications (e.g. drug delivery), it also would have been obvious to combine the Boone et al./Sinclair et al. taught plasticizer with the PLGA in Berggren et al. such that such a glass transition temperature was obtained.

Although Bergmann et al. teach that the composition of their invention can be shaped based on the container it occupies when at elevated temperature, they do not teach a particular shape for the device (see column 5 lines 59-66). Webber et al. teach a film as a particular form for a drug containing PLGA composition (see instant claim 23). Thus in view of these additional teachings of Webber et al. it would have been obvious to one of ordinary skill in the art at the time the invention was made to form the composition of Berggren et al. modified by Jain et al., Maspero, Maspero et al., and Boone et al./ Sinclair et al. into a film. Therefore claims 20-23 and 25-27 are obvious over Bergmann et al. in view of Webber et al., Jain et al., Maspero, Maspero et al., and Boone et al./ Sinclair et al.

Claims 20 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berggren et al in view of Webber et al., Jain, Maspero et al., Maspero, Boone et al., Sinclair et al., and Gravett et al.

Bergmann et al. in view of Webber et al., Jain et al., Maspero, Maspero et al., and Boone et al./ Sinclair et al. make obvious a composition consisting of amorphous PLGA, a plasticizer selected from the group consisting of lactic acid, lactic acid oligomers and mixtures thereof, and an active principle such that the plasticizer-polymer combination has a glass transition temperature equal to or below 15ºC (see ***Claim Rejections - 35 USC § 103*** of Claims 20-23 and 25-27 above). Although this modified reference teaches that the composition can be shaped based on the container it occupies when at elevated temperature, they do not teach a particular shape for the device. Gravett et al. teach layered implantable device in a sandwich configuration. The device of their invention is taught to have therapeutic agent in film form and mesh such that the film resides between two layers of mesh (see paragraph 12 lines 1-5, 8-10, and 14-19; instant claim 24). Further, Gravett et al. also teach that both the mesh material and carrier for the therapeutic agent in film form are PLGA (see paragraph 13 lines 1-3 and 11-17 and paragraph 16 lines 1-2 and 18-21; instant claim 24). In view of these teachings, it would have been obvious to one of ordinary skill in the art at the time the invention was made to form the invention of modified Bergman et al. reference into this sandwich configuration since that particular form was well within their technical grasp. Therefore claims 20 and 24 are obvious over Berggren et al in view of Webber et al., Jain, Maspero et al., Maspero, Boone et al., Sinclair et al., and Gravett et al.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615

/Caralynne Helm/
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